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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------|------------------|
| 10/623,228  | 07/18/2003  | Timothy J. Hagen     | 01160/1                 | 2720             |
| 7590  | 12/03/2004  |                      | EXAMINER                |                  |
| Pharmacia Corporation<br>Global Patent Department<br>5th Floor<br>575 Maryville Centre Drive<br>St. Louis, MO 63141 |             |                      | STOCKTON, LAURA LYNNE   |                  |
|   |             |                      | ART UNIT                | PAPER NUMBER     |
|   |             |                      | 1626                    |                  |
|   |             |                      | DATE MAILED: 12/03/2004 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                          |                     |  |
|------------------------------|--------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>   | <b>Applicant(s)</b> |  |
|                              | 10/623,228               | HAGEN ET AL.        |  |
|                              | <b>Examiner</b>          | <b>Art Unit</b>     |  |
|                              | Laura L. Stockton, Ph.D. | 1626                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 November 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-22 is/are pending in the application.
  - 4a) Of the above claim(s) 14-22 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-13 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

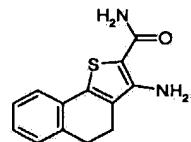
## DETAILED ACTION

**Claims 1-22 are pending in the application.**

### *Election/Restrictions*

Applicants' election with traverse of Group I, and the species of Example 1 on page 21 (reproduced below), in the reply filed on November 4, 2004 is acknowledged.

#### Examples 1



3-amino-4,5-dihydronaphtho[1,2-b]thiophene-2-carboxamide

The traversal is on the ground(s) of the restriction between Groups I, IV and VI. Applicants argue that methods claims should be rejoined upon allowance to a claim to the composition of matter.

In response, Group VI is not subject to the rejoinder practice since Group VI contains non-elected products. With respect to rejoinder of Groups I and IV, see the following. In accordance with M.P.E.P.

§821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

The scope of the elected invention that has been examined, inclusive of the species of Example 1, is as follows:

**A** is an unsubstituted  $(CH_2)_m$ ;

**R<sup>1</sup> and R<sup>2</sup>** are independently selected from the group consisting of:  
cyano, nitro, hydroxyl, alkyl, hydroxyalkyl, haloalkyl, alkoxy,  
haloalkoxy, amidine, guanidine, CONHR<sup>5</sup>, NHR<sup>5</sup> and

NHCXNHR<sup>5</sup>; and

all other variables are as defined.

The requirement is still deemed proper and is therefore made FINAL.

Subject matter not embraced by the above identified scope of the elected invention and claims 14-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions. Applicant timely traversed the restriction (election) requirement in the reply filed on November 4, 2004.

It is suggested that in order to advance prosecution, the non-elected subject matter be cancelled when responding to this Office Action.

***Priority***

Applicants' Provisional Application 60/397,052 filed July 19, 2002 has been reviewed because of intervening art. The entire genus of the instant claimed compounds of formula I in independent claim 1 could not be found in the provisional application. Further, the instant transmittal sheet indicates that the instant claimed application is a CIP of Provisional Application 60/397,052. Therefore, entire genus of the instant claimed compounds of formula I as instantly claimed is not afforded the benefit of the filing date of the provisional application.

***Information Disclosure Statement***

It is noted that an Information Disclosure Statement had not been filed at the time of this Office Action. It is suggested that if Applicants intend to file an IDS, that it be filed when responding to this Office Action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it is unclear what is meant by “carriers” of a compound of formula I (see line 3 of claim 1). In claim 1, under the definition of the B variable, the phrase “one or more substituent independently selected from” should be changed to “one or more substituents independently selected from”. Also in claim 1, under the definition of the B variable, a comma is needed after “haloalkyl”.  
claim 1, under the definition of the R<sup>4</sup> variable, the phrase “one or more radical selected from” should be changed to “one or more radicals selected from”. Claim 1 does not conform to M.P.E.P. 608.01(m) since each claim must end with a period and no other periods may be used

elsewhere in the claims except for abbreviations {e.g., see the period at the end of the R<sup>6</sup> definition}.

In claim 12, “amino” is misspelled in the compounds on page 89, lines 29-30 and page 90, lines 11-12.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 8 and 9 are rejected under 35 U.S.C. 102(a) as being anticipated by:

- a) CA Registry No. 443870-78-8 (entry date into the Registry file on STN – August 14, 2002);
- b) CA Registry No. 443870-77-7 (entry date into the Registry file on STN – August 14, 2002);
- c) CA Registry No. 443870-76-6 (entry date into the Registry file on STN – August 14, 2002);
- d) CA Registry No. 443870-75-5 (entry date into the Registry file on STN – August 14, 2002);
- e) CA Registry No. 443869-71-4 (entry date into the Registry file on STN – August 14, 2002);
- f) CA Registry No. 443869-70-3 (entry date into the Registry file on STN – August 14, 2002);
- g) CA Registry No. 443869-69-0 (entry date into the Registry file on STN – August 14, 2002);

- h) CA Registry No. 443869-68-9 (entry date into the Registry file on STN – August 14, 2002);
- i) CA Registry No. 443789-21-7 (entry date into the Registry file on STN – August 13, 2002);
- j) CA Registry No. 443787-76-6 (entry date into the Registry file on STN – August 13, 2002);
- k) CA Registry No. 443786-31-0 (entry date into the Registry file on STN – August 13, 2002);
- l) CA Registry No. 443661-19-6 (entry date into the Registry file on STN – August 12, 2002);
- m) CA Registry No. 443661-18-5 (entry date into the Registry file on STN – August 12, 2002);
- n) CA Registry No. 443661-17-4 (entry date into the Registry file on STN – August 12, 2002);
- o) CA Registry No. 443661-16-3 (entry date into the Registry file on STN – August 12, 2002);

- p) CA Registry No. 443661-15-2 (entry date into the Registry file on STN – August 12, 2002);
- q) CA Registry No. 443661-14-1 (entry date into the Registry file on STN – August 12, 2002);
- r) CA Registry No. 443121-48-0 (entry date into the Registry file on STN – August 8, 2002);
- s) CA Registry No. 443121-47-9 (entry date into the Registry file on STN – August 8, 2002);
- t) CA Registry No. 443121-46-8 (entry date into the Registry file on STN – August 8, 2002);
- u) CA Registry No. 443121-45-7 (entry date into the Registry file on STN – August 8, 2002);
- v) CA Registry No. 443121-44-6 (entry date into the Registry file on STN – August 8, 2002);
- w) CA Registry No. 443121-43-5 (entry date into the Registry file on STN – August 8, 2002);

- x) CA Registry No. 443121-42-4 (entry date into the Registry file on STN – August 8, 2002);
- y) CA Registry No. 443121-41-3 (entry date into the Registry file on STN – August 8, 2002);
- z) CA Registry No. 443121-40-2 (entry date into the Registry file on STN – August 8, 2002);
  - aa) CA Registry No. 443121-39-9 (entry date into the Registry file on STN – August 8, 2002);
  - ab) CA Registry No. 443121-38-8 (entry date into the Registry file on STN – August 8, 2002);
  - ac) CA Registry No. 443121-37-7 (entry date into the Registry file on STN – August 8, 2002);
  - ad) CA Registry No. 443119-53-7 (entry date into the Registry file on STN – August 8, 2002);
  - ae) CA Registry No. 443119-52-6 (entry date into the Registry file on STN – August 8, 2002);

- af) CA Registry No. 443119-51-5 (entry date into the Registry file on STN – August 8, 2002);
- ag) CA Registry No. 443119-50-4 (entry date into the Registry file on STN – August 8, 2002);
- ah) CA Registry No. 443119-49-1 (entry date into the Registry file on STN – August 8, 2002); or
- ai) CA Registry No. 443119-48-0 (entry date into the Registry file on STN – August 8, 2002).

Each of the above cited prior art references disclose at least one compound that is embraced by the instant claimed invention.

Claims 1-4, 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by:

- a) Rosowsky et al. {Journal of Medicinal Chemistry, (1973), 16(3), pages 191-194} – see compounds 2e, 2f and 2g on page 192, second column, middle of the page;
- b) Elslager et al. {Journal of Heterocyclic Chemistry, (August 1972), 9(4), pages 775-782} – see compounds 4 and 6 on page 776; or
- c) Bastian {U.S. Pat. 4,183,943} – see, for instance, Example 6 in column 4.

Each of the above cited prior art references disclose at least one compound that is embraced by the instant claimed invention.

Claims 1, 2 and 4-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Callahan et al. {WO 03/086309}.

Callahan et al. disclose, for instance, Example 5 on page 29 which is embraced by the instant claimed invention.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Callahan et al. {WO 03/086309} and Bastian {U.S. Pat. 4,183,943}, each taken alone or in combination with each other.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Applicants claim tricyclic containing thiophene compounds.

Callahan et al. (page 7; page 9, lines 6-16; page 12, starting at line 12 thru page 16; and especially Example 5 on page 29) and Bastian (column 1, lines 10-40; column 5, lines 9-17; column 6, lines 22-33; and especially Example 6 in column 4) each teach tricyclic containing thiophene compounds that are either structurally the same as (see above 102 rejections) or structurally similar to the instant claimed compounds.

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The difference between some of the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

*Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)*

The indiscriminate selection of “some” among “many” is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make

the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g. an anti-thrombin). Further, since Callahan et al. (page 9, lines 6-16) and Bastian (column 5, lines 9-17) each teach that the tricyclic containing thiophene compounds are useful in treating, for example, asthma, the combination of the two references would also teach Applicants' claimed invention.

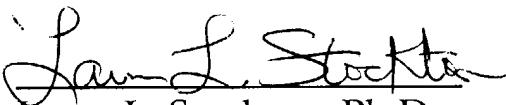
One skilled in the art would thus be motivated to prepare compounds embraced by the prior art to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial compounds which would be useful in treating inflammatory disorders. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art. A strong case of *prima facie* obviousness has been established.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to

2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.



Laura L. Stockton, Ph.D.  
Patent Examiner  
Art Unit 1626, Group 1620  
Technology Center 1600

November 24, 2004